2011 Durable Medical Equipment Criteria

Insulin Pump, Ambulatory: General[1, 2, 3]

CLIENT	D.O.B.	ID#	GROUP#
Diagnosis/ICD9	Sex M F (circle one)	Height	Weight
PCP/SPECIALIST	ID#	Telephone#	
VENDOR:	Telephone#	Authorization: / / to / /	

EQUIPMENT/INDICATIONS (choose one and see below)

☐ 100 Insulin pump (*E0784*)
☐ Indication Not Listed (Provide clinical justification below)

☐ 100 Insulin pump (*E0784*) **[All]**[4]
- ☐ 110 Insulin-requiring diabetes[5, 6]
- ☐ 120 Clinical presentation **[One or More]**[7, 8]
  - ☐ 121 Glycohemoglobin level ≥ 7% (i.e., HbA_{1c}, A1C)[9, 10]
  - ☐ 122 Blood glucose < 80 mg/dL or > 140 mg/dL before mealtimes[11]
  - ☐ 123 Dawn phenomenon blood glucose > 140 mg/dL[12]
  - ☐ 124 Hx of recurrent severe hypoglycemia/hypoglycemia unawareness[13]
- ☐ 130 Blood glucose testing ≥ 4x/day for ≥ 8 wks[14, 15]
- ☐ 140 Lifestyle requires flexibility (e.g., work/school, meal schedule, travel)[16]
- ☐ 150 Assessed by diabetes care team/specialist **[All]**[17, 18]
  - ☐ 151 Independent with insulin management/child supported by knowledgeable caregivers
  - ☐ 152 Patient/caregiver demonstrates knowledge of carbohydrate counting/meal planning[19]
  - ☐ 153 Motivated to assume responsibility for self-care/child's diabetes care[20]

Notes

(1)
An insulin pump is an external ambulatory infusion device. Insulin pump therapy, also known as continuous subcutaneous insulin infusion (CSII), is an option for managing insulin dependent diabetes. By continuous administration of short acting insulin at preselected rates, the insulin pump can improve the patient's glycemic control and decrease their risk of hyperglycemic complications (Diabetes Care 2010, 33 Suppl 1: S11-61).

(2)
Requests for a replacement insulin pump may be subject to organizational policy, but should take into account such factors as the patient's adherence to current pump therapy and potential improved glycemic control secondary to the additional features of the replacement pump.

(3)
ICD9 codes for diagnosis that may be appropriate for use of an ambulatory Insulin Pump include: 249.00-250.93.

(4)

Maintenance of near normal glycemia is the therapeutic goal of intensive therapy. A reduction of neuropathies, nephropathy, and cardiovascular complications (e.g., MI, stroke) has been documented in patients who achieve tight glycemic control (Diabetes Care 2010, 33 Suppl 1: S11-61). A comprehensive diabetes management program consists of frequent self-monitoring of blood glucose levels, administration of insulin by multiple daily injections or use of an insulin pump, adherence to a diet and exercise program, and involvement of a multidiscipline health support team (Dassau et al., Diabetes Care 2010, 33: 1249-54).

(5)

Type 1 (insulin dependent diabetes mellitus) diabetes is primarily due to pancreatic islet B-cell destruction causing the body to not produce insulin. It may be immune mediated or idiopathic. The type 1 diabetic is prone to extreme fluctuations of blood glucose causing ketoacidosis and severe hypoglycemia if not well managed (American Diabetes Association, Diabetes basics: Type 1. 2010).

(6)

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy and affects about 4% of all pregnant women. Insulin therapy is recommended during pregnancy when medical nutritional therapy fails to maintain self-monitored glucose levels (American Diabetes Association, Diabetes basics: What is Gestational Diabetes? 2010).

(7)

The insulin pump criteria address both pediatric and adult diabetes populations.

(8)

Controlling hypoglycemic episodes (plasma glucose level < 60 mg/dL) is important in diabetes management because of the potentially devastating effects (e.g., seizure or coma) on the brain. Likewise, controlling hyperglycemia over the long term has been associated with a decrease in retinopathy, nephropathy, and neuropathy (Dassau et al., Diabetes Care 2010, 33: 1249-54).

(9)

Glycohemoglobin is hemoglobin that has been altered by the attachment of glucose. HbA_{1c} is the most common type of glycohemoglobin, comprising 80% of the total glycohemoglobin, and is frequently measured in diabetic patients. Higher levels indicate poor diabetes control. Currently, the goal for diabetics is a glycohemoglobin of less than 7% (American Diabetes Association, Diabetes Care 2008; 31 Suppl 1: S12-54).

(10)

The Diabetes Control and Complications Trial (DCCT) demonstrated that in patients with Type 1 diabetes the risk of development or progression of retinopathy, nephropathy, and neuropathy is reduced 50% to 75% by intensive treatment when compared with conventional treatment regimens. Lowering A1C to an average of approximately 7% has clearly been shown to reduce microvascular and neuropathic complications of diabetes and, possibly, macrovascular disease. Therefore, the A1C goal for nonpregnant adults in general is < 7% (Diabetes Care 2010, 33 Suppl 1: S11-61).

(11)

Preprandial target goals for patients with diabetes are 80 to 120 mg/dL. Changes in the treatment plan are suggested when the average levels are < 80 mg/dL or > 140 mg/dL (Centers for Disease Control and Prevention, 2010).

(12)-DEF:

Dawn phenomenon is an early morning increase in blood glucose seen in many patients with Type 1 diabetes. It is caused by a lack of plasma insulin from the previous evening's insulin dose and an increase in insulin resistance secondary to endogenous nocturnal growth hormone secretion (Diabetes Care 2010, 33 Suppl 1: S11-61).

(13)

Controlling hypoglycemic episodes (glucose level < 60 mg/dL) is important in diabetes management because of the potentially devastating effects (e.g., seizure or coma) on the brain. Hypoglycemia unawareness is the clinical syndrome where autonomic response to falling blood sugar is reduced or absent. Without internal feedback to recognize that his/her blood sugar is low, the patient is unable to take the appropriate action of ingesting food or drink (Dassau et al., Diabetes Care 2010, 33: 1249-54).

(14)

Testing of blood glucose four or more times a day may be required to reach A1C targets safely without hypoglycemia (Diabetes Care 2010, 33 Suppl 1: S11-61).

(15)

Blood glucose results should be recorded even if the glucometer has a memory feature. This record can be used by the family and the health care team to observe patterns and adjust insulin dosages (Diabetes Care 2010, 33 Suppl 1: S11-61).

(16)
Lifestyle flexibility refers to the patient who due to work, travel, or physical activity requires greater flexibility with regard to meal schedules and insulin administration.

(17)
Continuous subcutaneous insulin infusion is appropriate for the patient who is well motivated to improve glucose control and willing to work with his/her health care providers (multidisciplinary team that may include a diabetologist or endocrinologist, diabetes nurse educator, dietitian, social worker, and other physician specialists) in assuming substantial responsibility for his/her day-to-day care. He/she must be able to demonstrate appropriate pump usage, monitoring of blood glucose levels, and using the data to manage his/her diabetes (Diabetes Care 2010, 33 Suppl 1: S11-61).

(18)
To determine if a patient is suitable for pump therapy a diabetes nurse educator would assess the patient's motivation, comprehension of the disease process, and complete a psychosocial evaluation. Those with psychological problems tend not to succeed with continuous subcutaneous insulin infusion therapy. Successful implementation is based upon the patient and caregivers having proper motivation, cognitive and problem solving skills, as well as maturity and financial stability (Diabetes Care 2010, 33 Suppl 1: S11-61).

(19)
The dietitian, as part of the diabetes health care team, provides instruction and assesses the patient's understanding of carbohydrate counting and meal planning so that insulin dosages can be calculated based upon the amount of carbohydrate consumed (Diabetes Care 2010, 33 Suppl 1: S11-61).

(20)
Caution should be exercised in children less than 13 years old who are started on intensive diabetes treatment programs. Children utilizing pump therapy require continuous supervision by parents and caretakers that are able to understand the pump technology, measure blood glucose levels, make appropriate adjustments, and work closely with the diabetes staff (Diabetes Care 2010, 33 Suppl 1: S11-61).